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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,222	SHUGART, JACK I.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☒ Claim(s) 2-12 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/5/04 & 7/8/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

Claims 1-19 are presented for examination.

Applicant's Information Disclosure Statements (IDS) filed May 5, 2004 (one page total) and July 8, 2005 (one page total) have each been received and entered into the application. As reflected by the attached, completed copies of forms PTO/SB/08A (two pages total), the Examiner has considered the cited references.

Objections to the Claims

Claim 2 is objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit, either physically or materially, the subject matter of the composition recited in previous claim 1. The recitation of "wherein said animal is a person" is merely a recitation of the host in whom the function of rendering the composition aversive to an animal when ingested or inhaled would be accomplished. Thus, such a limitation amounts to no more than a recitation of the intended use of the composition and fails to impart any physical or otherwise material limitation to the composition of claim 1 that is not already present.

Claims 3-12 are objected to for lacking antecedent basis for the phrase "euthanasia composition" in line 1 of each of the claims. Parent claim 1 does not recite such a limitation, but rather states, "injectable euthanasia composition". See 37 C.F.R. 1.75(d)(1) and MPEP §608.01(o).

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and

distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expression "between about 3 to 1 and about 6 to 1" (see present claim 8, for example) is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a particular ratio is included in or excluded from the present claims and what degree of variability outside the recited ranges is within the scope of the claims. Furthermore, the phrase "between" has been noted in present claims 8-12, which indicates that the ratio is greater than 3 to 1 but less than 6 to 1. However, the presence of the word "about" denotes that the ratio may be slightly greater than or slightly less than the recited upper or lower limit. Thus, it is not clear which is meant to be the limiting term. As a result, the public would not be reasonably informed of the boundaries of what constitutes infringement of the present claims. In light of such a conclusion, the claims do not meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are, therefore, properly rejected.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al. (U.S. Patent No. 5,290,775; 1994) in view of Baker (U.S. Patent No. 5,720,951; 1998), Oshlack et al. (U.S. Patent Application Publication 2003/0064099; April 2003), Minkoff (U.S. Patent No. 4,005,038; 1977), Komer (U.S. Patent No. 5,962,536; 1999) and Sawyer et al. (U.S. Patent No. 5,281,611, 1994).

Sawyer et al. teaches an injectable aqueous solution, in which a cardiotoxic compound, selected from the group consisting of a quinacrine compound or a chloroquine compound (e.g., chloroquine diphosphate; see Table 2 at col.6, line 26; considered to be inclusive of quinacrine or chloroquine base as recited in present claims 10 and 12), is in combination with lidocaine, either in base or water soluble salt form, and further in combination with gamma-hydroxybutramide, wherein the solution contains a ratio of gamma-hydroxybutramide of between about 3 to 1 and 6 to 1 and a ratio of lidocaine to gamma-hydroxybutramide between about 0.01 and 0.015 to 1, in an amount sufficient to produce euthanasia (col.3, lines 36-50; see present claims 1 and 8-10). Sawyer et al. further teaches that the gamma-hydroxybutramide of the composition may be dissolved in a water immiscible liquid solubilizing agent, such as ethanol or denatured alcohol

(col.4, lines 25-29), and formulated in combination with a water soluble chloroquine compound and a lidocaine compound, where the ratio of gamma-hydroxybutramide to chloroquine is between about 3 to 1 and 6 to 1 and the ratio of lidocaine compound to gamma-hydroxybutramide compound is between about 0.01 and 0.015 to 1 (col.3, lines 51-64; see present claims 1 and 11-12). Sawyer et al. discloses a method of introducing such a combination of active agents into a mammal, wherein euthanasia occurs in the mammal (col.3, lines 16-26; see present claim 13). The reference also teaches that an analgesic may be combined with a tranquilizer or other anesthetics known in the art and administered prior to euthanasia to prevent agonal breathing (col.4, line64-col.5, line 2; see present claims 15 and 17-18).

The differences between the Sawyer et al. reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the use of a taste aversive agent, particularly denatonium benzoate (see present claims 1-18) and the method for making a taste aversive injectable euthanasia composition (see present claim 19);

(ii) the use of the anesthetic propofol (see present claim 16);

(iii) the use of chloroquine or quinacrine salts or quinacrine hydrochloride (see present claims 8 and 10; and

(iv) the presently claimed amounts of denatonium benzoate (see present claims 4-6).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) Although it is acknowledged that Sawyer et al. is silent as to the use of a taste aversive agent, such as the bittering agent denatonium benzoate, it was well known in the art to include such a compound in toxic compositions and/or pharmaceutical compositions containing commonly abused active agents (i.e., opioid analgesics), in order to deter human consumption of the toxic compound(s) by causing an unpleasant taste.

In this regard, Baker (U.S. Patent No. 5,720,951; 1998), Oshlack et al. (U.S. Patent Application Publication No. 2003/0064099; April 2003) and Minkoff (U.S. Patent No. 4,005,038; 1977) are cited. Baker teaches the use of the bittering agent denatonium benzoate or another salt of the denatonium cation in rodenticide bait, in order to deter human consumption of the bait, which is toxic to humans (see Baker, col.5, lines 16-21). Oshlack et al. teaches the use of denatonium benzoate as a bittering agent that may be incorporated into dosage forms containing commonly abused therapeutic agents, i.e., opioid analgesics, in order to discourage an abuser from tampering with and attempting to swallow or inhale the dosage form (see Oshlack et al., paragraphs [0021], [0038] and [0044]). Minkoff also teaches the use of denatonium benzoate in a coating composition to be applied over previously coated surfaces, such as the interior surfaces of older dwellings wherein the paint contained lead and other toxic substances, to deter anyone who may try to chew, suck, lick or eat the dried paint film by rendering the coating repulsive in taste (see Minkoff, col.2, lines 9-30 and col.3, lines 19-24). Furthermore, each of the above-cited references teaches that the bittering agent (i.e., denatonium benzoate) was simply mixed into the toxic composition (see Baker, col.5, lines 50-60; Oshlack et al., paragraphs [0081-0082]; and Minkoff, examples at cols.3-5).

In light of such teachings, it would have been obvious to the skilled artisan to employ a bittering agent such as denatonium benzoate in the euthanasia formulation disclosed by Sawyer

et al. in order to deter human consumption of the toxic composition, particularly to protect those mammals who are not the intended recipients of the euthanizing composition from accidental (or intentional, in the case of drug abuse) ingestion. Furthermore, in light of what was already known in the art regarding the inclusion of denatonium benzoate into active compositions, it would have been obvious to the skilled artisan to simply mix such a bittering agent into the active euthanasia formulation disclosed by Sawyer et al. for the same reasons stated above in the preceding paragraph.

(ii) Sawyer et al. broadly teaches the combination of analgesics, tranquilizers or anesthetics known in the art with the disclosed euthanasia composition, comprising, for example, a cardiotoxic chloroquine or quinacrine compound, lidocaine, and gamma-hydroxybutramide (see Sawyer et al., col.4, line 64-col.5, line 2). While the reference is silent as to the specific use of propofol, as presently recited in claim 16, Komer (U.S. Patent No. 5,962,536; 1999) teaches that the compound propofol was well known in the art as an extremely fast-acting anesthetic of short duration and useful for both medical and veterinary use (see Komer, col.1, lines 28-33). Komer further discloses that propofol was known in the art to be particularly useful in fast-acting, humane, veterinary euthanasia injectable compositions because it provided rapid onset of anesthesia to minimize the discomfort experienced by the animal as the lethal effects of the euthanizing toxin took hold (see Komer, col.1, lines 56-59 and col.2, lines 18-21). Thus, it would have been obvious to the skilled artisan to employ propofol as the anesthetic in the composition disclosed by Sawyer et al. because the compound was well known in the art as an anesthetic amenable to inclusion in euthanizing compositions. The skilled artisan would have been motivated to use such a compound because the compound achieves rapid onset of its

therapeutic effects, thereby minimizing the discomfort associated with the euthanizing process and promoting humane euthanasia.

(iii) Sawyer et al. broadly teaches the use of a cardiotoxic chloroquine compound or a quinacrine compound (considered to read on chloroquine or quinacrine base) in the disclosed composition, but is silent as the express use of chloroquine or quinacrine salts, particularly quinacrine hydrochloride. However, the broad teaching of chloroquine or quinacrine compounds is considered to be inclusive of all compounds and related compounds that are structurally similar as to indicate to the skilled artisan that such compounds would be reasonably expected to exert the same or a substantially similar effect to that of the compound itself. For this reason, the skilled artisan would have recognized that any of the chloroquine or quinacrine salts, particularly quinacrine hydrochloride, would have been reasonably expected to be equally as effective as the specific chloroquine or quinacrine compounds disclosed by Sawyer et al. (e.g., chloroquine diphosphate; see Table 2 of Sawyer et al. at col.6, line 26).

In further support of this conclusion, the Examiner relies on the teachings of Sawyer et al. (U.S. Patent No. 5,281,611, 1994), who specifically teaches that chloroquine salts and quinacrine salts, particularly quinacrine hydrochloride, were compounds well known in the art as chloroquine or quinacrine compounds, respectively (see Sawyer et al., col.2, line 62-col.3, line 2 and col.7, claim 2), and the use of such compounds would have been a matter well within the purview of the skilled artisan for the same reasons as stated above in the preceding paragraph.

(iv) The determination of the optimum amounts of denatonium benzoate to achieve adequate taste aversion to the presently claimed euthanasia composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet, route

of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the volume of the formulation that is required to achieve euthanasia. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence or direction to the contrary, the currently claimed amounts are not seen to be inconsistent with the amounts that would have been determined by one of ordinary skill in the relevant art.

Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the instant claims are drawn to ppm by volume amounts, and not percentages, such motivation is nonetheless relevant to the presently claimed subject matter.

Conclusion

Rejection of claims 1-19 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
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Art Unit 1614

August 17, 2005

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